IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL, INC. and ARIUS TWO, INC. Plaintiffs, v. ALVOGEN PB RESEARCH & DEVELOPMENT LLC, ALVOGEN MALTA OPERATIONS LTD., ALVOGEN PINE BROOK LLC, ALVOGEN, INC., and ALVOGEN GROUP, INC., Defendants.	Civil Action No. 1:18-cv-01395-CFC

DEFENDANTS' ANSWER AND AFFIRMATIVE DEFENSES

Defendants Alvogen PB Research & Development LLC ("Alvogen PB"), Alvogen Malta Operations Ltd. ("Alvogen Malta"), Alvogen Pine Brook LLC ("Alvogen Pine Brook"), Alvogen, Inc., and Alvogen Group, Inc. ("Alvogen Group") (collectively, "Alvogen"), by and through their undersigned attorneys, hereby answer each of the numbered paragraphs of the Complaint filed September 7, 2018, by Plaintiffs BioDelivery Sciences International, Inc. ("BDSI"), and Arius Two, Inc. ("Arius") (collectively, "Plaintiffs"). Except as expressly admitted below, Alvogen denies each allegation of Plaintiffs' Complaint.

1. Alvogen admits that Plaintiffs purport to bring this action under the patent laws of the United States. Alvogen admits that this action pertains, at least in part, to the pharmaceutical drug product Belbuca®. Alvogen denies the remaining allegations in paragraph 1.

JURISDICTION AND PARTIES

2. Alvogen admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies BDSI as the applicant for New Drug Application ("NDA") No. 207932 for Belbuca®. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2 and therefore denies them.

3. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies them.

4. Admitted.

5. Alvogen admits that Alvogen PB is a pharmaceutical company. Alvogen denies the remaining allegations in paragraph 5.

6. Paragraph 6 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen PB for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 6.

7. Paragraph 7 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen PB for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 7.

8. Paragraph 8 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen PB for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 8.

9. Admitted.

10. Paragraph 10 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Malta for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 10.

11. Paragraph 11 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Malta for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 11.

12. Paragraph 12 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen admits that Alvogen Malta asserted counterclaims in *Pernix Ireland Pain DAC. et al. v. Alvogen Malta Operations, Ltd*., C.A. No. 1:1-cv-00139-GMS (D. Del. 2016) and did not contest personal jurisdiction for the limited purpose of that action only. Alvogen denies the remaining allegations in paragraph 12.

13. Paragraph 13 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Malta for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 13.

14. Denied.

15. Alvogen admits that Alvogen Pine Brook is a Delaware corporation having a place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058. Alvogen denies the remaining allegations in paragraph 15.

16. Alvogen admits that Alvogen Pine Brook is a pharmaceutical company. Alvogen denies the remaining allegations in paragraph 16.

17. Paragraph 17 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Pine Brook for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 17.

18. Paragraph 18 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Pine Brook for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 18.

19. Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen admits that Alvogen Pine Brook filed a complaint in *Alvogen Pine Brook LLC v. Noven Pharm., Inc. et al*., C.A. No. 1:16-cv-00395-LPS (D. Del. 2016). Alvogen further admits that Alvogen Pine Brook asserted counterclaims in *Noven Pharm., Inc. v. Alvogen Pine Brook LLC, Alvogen, Inc., and 3M Co.,* C.A. No. 1:17-cv-01429-LPS (D. Del. 2017) and *Purdue Pharma LP et al. v. Alvogen Pine Brook LLC and Actavis Labs. FL, Inc*. C.A. No. 1:17-cv-01369-TBD (D. Del. 2017) and did not contest personal jurisdiction for the limited purpose of those actions only. Alvogen denies the remaining allegations in paragraph 19.

20. Paragraph 20 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Pine Brook for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 20.

21. Alvogen admits that Alvogen, Inc. is a Delaware corporation having a place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058. Alvogen denies the remaining allegations in paragraph 21.

22. Alvogen admits that Alvogen, Inc. is a pharmaceutical company. Alvogen denies the remaining allegations in paragraph 22.

23. Paragraph 23 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen, Inc. for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 23.

24. Paragraph 24 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen, Inc. for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 24.

25. Paragraph 25 contains legal conclusions to which no response is required. To the extent that a response is required, it is admitted that Alvogen, Inc. asserted counterclaims in *Noven Pharm., Inc. v. Alvogen Pine Brook LLC, Alvogen, Inc., and 3M Co.*, C.A. No. 1:17-cv-01429-LPS (D. Del. 2017) and did not contest personal jurisdiction for the limited purpose of that action only. Alvogen denies the remaining allegations in paragraph 25.

26. Paragraph 26 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen, Inc. for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 26.

27 Alvogen admits that Alvogen Group is a Delaware corporation having a place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058. Alvogen denies the remaining allegations in paragraph 27.

28. Alvogen admits that Alvogen Group is a pharmaceutical company. Alvogen denies the remaining allegations in paragraph 28.

29. Paragraph 29 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Group for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 29.

30. Paragraph 30 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Group for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 30.

31. Paragraph 31 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen admits that Alvogen Group asserted counterclaims in *Reckitt Benckiser Pharm., Inc. et al. v. Alvogen Pine Brook, Inc. and Alvogen Grp., Inc.*, C.A. No. 1:13-cv-02003-RGA (D. Del. 2013) and did not contest personal jurisdiction for the limited purpose of that action only. Alvogen denies the remaining allegations in paragraph 31.

32. Denied.

33. Paragraph 33 contains legal conclusions to which no response is required. To the extent that a response is required, Alvogen does not contest that this Court has personal jurisdiction over Alvogen Group for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 33.

34. Denied.

35. Alvogen admits that Plaintiffs purport to bring this action under the patent laws of the United States. Alvogen does not contest subject matter jurisdiction for the limited purpose of this action only. Alvogen does not contest venue for the limited purpose of this action only. Alvogen denies the remaining allegations in paragraph 35.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of U.S. Patent No. 8,147,866 under 35 U.S.C § 271(e)(2))

36. Alvogen repeats and realleges its answers to paragraphs 1-35 as if fully set forth herein.

37. Alvogen admits that the '866 patent states that it was issued on April 3, 2012. Alvogen admits that the '866 patent is entitled "Transmucosal Delivery Devices with Enhanced Uptake." Alvogen admits that Andrew Finn and Niraj Vasisht are listed as inventors on the face of the '866 patent. Alvogen admits that BDSI is listed as the assignee on the face of the '866 patent. Alvogen admits that a purported copy of the '866 patent is attached to the Complaint as Exhibit A. Alvogen denies that the '866 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 37 and therefore denies them.

38. Alvogen admits that the Orange Book identifies NDA No. 207932 as directed to Belbuca®. Alvogen admits that the Orange Book entry for NDA No. 207932 identifies the FDA approval date as October 23, 2015. Alvogen admits that the '866 patent is identified in the Orange Book entry for NDA No. 207932. Alvogen admits that the prescribing information for Belbuca® states that Belbuca® "is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Alvogen admits that the prescribing information for Belbuca® states

that Belbuca® "provid[es] transmucosal delivery of buprenorphine hydrochloride." Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 38 and therefore denies them.

39. Alvogen admits that ANDA No. 211594 was submitted to FDA under 21 U.S.C. § 355(j) in order to obtain approval to engage in the commercial manufacture, use, or sale of buprenorphine buccal film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg) in the United States before the expiration of the '866 patent. Alvogen denies the remaining allegations in paragraph 39.

40. Alvogen admits that ANDA No. 211594 contains a Paragraph IV certification asserting, *inter alia*, that the '866 patent is invalid, unenforceable, and/or will not be infringed by the generic product proposed in the ANDA. Alvogen denies the remaining allegations in paragraph 40.

41. Alvogen admits that a letter dated July 27, 2018 ("Notice Letter") was sent to, *inter alia*, Plaintiff BDSI. Alvogen admits that the Notice Letter notified Plaintiffs that ANDA No. 211594 was submitted to FDA and provided information pursuant to 21 U.S.C. §§ 355(j)(2)(B)(ii). Alvogen denies the remaining allegations in paragraph 41.

42. Denied.

43. Alvogen admits that ANDA No. 211594 was submitted to FDA seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine buccal film. Alvogen denies the remaining allegations in paragraph 43.

44. Denied.

45. Denied.

46. Denied.

47. Alvogen admits that the Complaint was filed on September 7, 2018. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 47 and therefore denies them.

48. Denied.

49. Denied.

COUNT II FOR PATENT INFRINGEMENT
(Infringement of U.S. Patent No. 9,655,843 under 35 U.S.C § 271(e)(2))

50. Alvogen repeats and realleges its answers to paragraphs 1-35 as if fully set forth herein.

51. Alvogen admits that the '843 patent states that it was issued on May 23, 2017. Alvogen admits that the '843 patent is entitled "Transmucosal Delivery Devices with Enhanced Uptake." Alvogen admits that Andrew Finn and Niraj Vasisht are listed as inventors on the face of the '843 patent. Alvogen admits that BDSI is listed as the assignee on the face of the '843 patent. Alvogen admits that a purported copy of the '843 patent is attached to the Complaint as Exhibit B. Alvogen denies that the '843 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 51 and therefore denies them.

52. Alvogen admits that the Orange Book identifies NDA No. 207932 as directed to Belbuca®. Alvogen admits that the Orange Book entry for NDA No. 207932 identifies the FDA approval date as October 23, 2015. Alvogen admits that the '843 patent is identified in the Orange Book entry for NDA No. 207932. Alvogen admits that the prescribing information for Belbuca® states that Belbuca® "is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Alvogen admits that the prescribing information for Belbuca® states

that Belbuca® "provid[es] transmucosal delivery of buprenorphine hydrochloride." Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 52 and therefore denies them.

53. Alvogen admits that ANDA No. 211594 was submitted to FDA under 21 U.S.C. § 355(j) in order to obtain approval to engage in the commercial manufacture, use, or sale of buprenorphine buccal film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg) in the United States before the expiration of the '843 patent. Alvogen denies the remaining allegations in paragraph 53.

54. Alvogen admits that ANDA No. 211594 contains a Paragraph IV certification asserting, *inter alia*, that the '843 patent is invalid, unenforceable, and/or will not be infringed by the generic product proposed in the ANDA. Alvogen denies the remaining allegations in paragraph 54.

55. Alvogen admits that a letter dated July 27, 2018 ("Notice Letter") was sent to, *inter alia*, Plaintiff BDSI. Alvogen admits that the Notice Letter notified Plaintiffs that ANDA No. 211594 was submitted to FDA and provided information pursuant to 21 U.S.C. §§ 355(j)(2)(B)(ii). Alvogen denies the remaining allegations in paragraph 55.

56. Denied.

57. Alvogen admits that ANDA No. 211594 was submitted to FDA seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine buccal film. Alvogen denies the remaining allegations in paragraph 57.

58. Denied.

59. Denied.

60. Denied.

61. Alvogen admits that the Complaint was filed on September 7, 2018. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 61 and therefore denies them.

62. Denied.

63. Denied.

COUNT III FOR PATENT INFRINGEMENT
(Infringement of U.S. Patent No. 9,901,539 under 35 U.S.C § 271(e)(2))

64. Alvogen repeats and realleges its answers to paragraphs 1-35 as if fully set forth herein.

65. Alvogen admits that the '539 patent states that it was issued on February 27, 2018. Alvogen admits that the '539 patent is entitled "Transmucosal Drug Delivery Devices for Use in Chronic Pain Relief." Alvogen admits that Andrew Finn and Niraj Vasisht are listed as inventors on the face of the '539 patent. Alvogen admits BDSI is listed as the assignee on the face of the '539 patent. Alvogen admits that a purported copy of the '539 patent is attached to the Complaint as Exhibit C. Alvogen denies that the '539 patent was duly and legally issued. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 65 and therefore denies them.

66. Alvogen admits that the Orange Book identifies NDA No. 207932 as directed to Belbuca®. Alvogen admits that the Orange Book entry for NDA No. 207932 identifies the FDA approval date as October 23, 2015. Alvogen admits that the '539 patent is identified in the Orange Book entry for NDA No. 207932. Alvogen admits that the prescribing information for Belbuca® states that Belbuca® "is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Alvogen admits that the prescribing information for Belbuca® states

that Belbuca® "provid[es] transmucosal delivery of buprenorphine hydrochloride." Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 66 and therefore denies them.

67. Alvogen admits that ANDA No. 211594 was submitted to FDA under 21 U.S.C. § 355(j) in order to obtain approval to engage in the commercial manufacture, use, or sale of buprenorphine buccal film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg) in the United States before the expiration of the '539 patent. Alvogen denies the remaining allegations in paragraph 67.

68. Alvogen admits that ANDA No. 211594 contains a Paragraph IV certification asserting, *inter alia*, that the '539 patent is invalid, unenforceable, and/or will not be infringed by the generic product proposed in the ANDA. Alvogen denies the remaining allegations in paragraph 68.

69. Alvogen admits that a letter dated July 27, 2018 ("Notice Letter") was sent to, *inter alia*, Plaintiff BDSI. Alvogen admits that the Notice Letter notified Plaintiffs that ANDA No. 211594 was submitted to FDA and provided information pursuant to 21 U.S.C. §§ 355(j)(2)(B)(ii). Alvogen denies the remaining allegations in paragraph 69.

70. Denied.

71. Alvogen admits that ANDA No. 211594 was submitted to FDA seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine buccal film. Alvogen denies the remaining allegations in paragraph 71.

72. Denied.

73. Denied.

74. Denied

75. Alvogen admits that the Complaint was filed on September 7, 2018. Alvogen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 75 and therefore denies them.

76. Denied.

77. Denied.

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '866 Patent Under 35 U.S.C §§ 271(a), (b), and/or (c))

78. Alvogen repeats and realleges its answers to paragraphs 1-49 as if fully set forth herein.

79. Alvogen admits that Plaintiffs purport to bring this action under the patent laws of the United States and the Declaratory Judgment Act. Alvogen denies the remaining allegations in paragraph 79.

80. Denied.

81. Denied

82. Alvogen admits that ANDA No. 211594 was submitted to FDA seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine buccal film. Alvogen denies the remaining allegations in paragraph 82.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT V FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '843 Patent Under 35 U.S.C §§ 271(a), (b), and/or (c))

87. Alvogen repeats and realleges its answers to paragraphs 1-35 and 50-63 as if fully set forth herein.

88. Alvogen admits that Plaintiffs purport to bring this action under the patent laws of the United States and the Declaratory Judgment Act. Alvogen denies the remaining allegations in paragraph 88.

89. Denied.

90. Denied.

91. Alvogen admits that ANDA No. 211594 was submitted to FDA seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine buccal film. Alvogen denies the remaining allegations in paragraph 91.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

COUNT VI FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '539 Patent Under 35 U.S.C §§ 271(a), (b), and/or (c))

96. Alvogen repeats and realleges its answers to paragraphs 1-35 and 64-77 as if fully set forth herein.

97 Alvogen admits that Plaintiffs purport to bring this action under the patent laws of the United States and the Declaratory Judgment Act. Alvogen denies the remaining allegations in paragraph 97.

98. Denied.

99. Alvogen admits that ANDA No. 211594 was submitted to FDA seeking approval to engage in the commercial manufacture, use, and/or sale of buprenorphine buccal film. Alvogen denies the remaining allegations in paragraph 99.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

PRAYER FOR RELIEF

Alvogen denies that Plaintiffs are entitled to any remedy or relief, including those requested in the complaint.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiffs' Complaint, Alvogen states the following affirmative defenses:

First Affirmative Defense

The claims of the '866, '843, and '539 patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Second Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of buprenorphine buccal film that is the subject of ANDA No. 211594 will not infringe, directly or indirectly, any valid or enforceable claim of the '866, '843, and '539 patents.

Third Affirmative Defense

The submission of ANDA No. 211594 has not infringed, and will not infringe, directly or indirectly, any valid and/or enforceable claim of the '866, '843, and '539 patents.

Fourth Affirmative Defense

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fifth Affirmative Defense

Plaintiffs lack standing to assert the claims of the 866, '843, and '539 patents.

Sixth Affirmative Defense

The relief requested in Plaintiffs' Complaint is barred by the doctrine of estoppel and/or waiver.

Seventh Affirmative Defense

Alvogen's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

HEYMAN ENERIO
GATTUSO & HIRZEL LLP

/s/ Dominick T. Gattuso
Dominick T. Gattuso (#3630)
300 Delaware Avenue, Suite 200
Wilmington, DE 19801
(302) 472-7300
dgattuso@hegh.law

Attorneys for Defendants Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen Inc., and Alvogen Group, Inc.

OF COUNSEL:

LEYDIG, VOIT & MAYER, LTD.
Steven H. Sklar
Gregory C. Bays
Two Prudential Plaza
180 N. Stetson Ave., Suite 4900
Chicago, IL 60601
(312) 616-5600
ssklar@leydig.com
gbays@leydig.com

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